

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A method for the detection of a renal tubular cell injury in a mammal, including an ischemic renal injury and a nephrotoxic injury, comprising the steps of:

- 1) (a) obtaining a urine sample from a mammalian subject that is suspected of having or being prone to develop a renal tubular cell injury;
- 2) (b) contacting the urine sample with an antibody for ~~a renal tubular cell injury biomarker, the biomarker comprising NGAL neutrophil gelatinase-associated lipocalin (NGAL)~~, to allow formation of a complex of the antibody and the biomarker NGAL; and
- 3) (c) detecting the antibody biomarker antibody-NGAL complex.

2. (currently amended) The method according to Claim 4 30 wherein the urine sample comprises a plurality of urine samples from the subject ~~is that are obtained intermittently or continuously~~.

3. (currently amended) The method according to Claim 2 wherein the plurality of urine samples are obtained continuously.

4. (currently amended) The method according to Claim 4 31 wherein the step of detecting the antibody-biomarker antibody-NGAL complex comprises contacting the complex with a second antibody for detecting the biomarker NGAL.

5. (currently amended) The method according to Claim 4 30 wherein the mammalian subject is a human patient.

6. (currently amended) A method of monitoring the effectiveness of a treatment for a renal tubular cell injury, comprising the steps of:

1) ~~providing a treatment to a mammalian subject experiencing a renal tubular cell injury;~~

2) (a) ~~detecting the presence of neutrophil gelatinase-associated lipocalin (NGAL) in a obtaining at least one post treatment urine sample obtained from a mammalian subject the subject that experienced a renal tubular cell injury and that has received a treatment for the renal tubular cell injury; and~~

3) ~~detecting for the presence of a biomarker for the renal tubular cell injury in the post-treatment urine sample~~

(b) ~~evaluating the renal tubular cell injury status of the subject based on the level of NGAL present in the post-treatment urine sample to determine the effectiveness of the treatment.~~

7. (canceled)

8. (currently amended) The method according to Claim 6, further comprising the step of obtaining one or more subsequent post-treatment urine samples, wherein the ~~progress of the treatment is evaluated step of providing treatment is continued until the presence of the biomarker in the subsequent post treatment urine samples is not detected.~~

9. (currently amended) The method according to Claim 6 ~~31~~ wherein the ~~step of detecting comprises the steps of:~~

~~i) contacting the urine sample with antibody is a capture antibody for the biomarker NGAL to allow formation of a complex of the antibody and the biomarker; and~~

~~ii) detecting the antibody biomarker complex.~~

10. (currently amended) The method according to Claim 9 wherein the step of detecting the ~~antibody- biomarker antibody-NGAL~~ complex comprises the steps of:

- (1) separating any unbound material of the urine sample from the capture ~~antibody- biomarker antibody-NGAL~~ complex;
- (2) contacting the capture ~~antibody- biomarker antibody-NGAL~~ complex with a second antibody for detecting the ~~biomarker NGAL~~, to allow formation of a second complex between the ~~biomarker and the second antibody and the capture antibody-NGAL complex~~;
- (3) separating any unbound second antibody from the ~~biomarker second second~~ antibody complex; and
- (4) detecting the second antibody of the ~~biomarker second second~~ antibody complex.

11. (currently amended) The method according to Claim 10 wherein the step i) comprises the step of contacting the urine sample with a media having affixed thereto the ~~first~~ capture antibody.

12 – 23 (cancelled)

24. (currently amended) A method of identifying the extent of a renal tubular cell injury, including an ischemic renal injury and a nephrotoxic injury, caused by an event, comprising the steps of:

- 1) (a) detecting in a obtaining at least one urine sample from a mammalian subject[[;]] that experienced the event
- 2) detecting in the urine sample the presence of [[a biomarker for a renal tubular cell injury]] neutrophil gelatinase-associated lipocalin (NGAL); and
- 3) (b) determining the extent of the renal tubular cell injury based on the time for onset of the presence of the biomarker NGAL in the urine sample, relative to the time of the event.

25. (canceled)

26. (original) The method according to Claim 24 wherein the event is a surgical procedure.

27. (currently amended) The method according to Claim 24 wherein the event is selected from the group consisting of an event that causes diminished blood supply to the kidneys; or impaired heart function, a surgical procedure procedures, an event that causes the admission of the mammalian subject to an patients in intensive care unit units, and the administration of pharmaceuticals, radiocontrast dyes, or other medicament substances to the subject.

28. (currently amended) A method for the detection of a renal tubular cell injury, including an ischemic renal injury and a nephrotoxic injury, in a mammal mammalian subject, comprising the steps of:

1) (a) contacting [[obtaining]] a urine sample comprising up to 1 milliliter of the first urine obtained from a mammalian subject within 24 hours of an event that causes renal tubular cell injury to the subject[[:]]

2) contacting the urine sample with an antibody for neutrophil gelatinase-associated lipocalin (NGAL) a biomarker for a renal tubular cell injury, to allow formation of a complex of the antibody and NGAL; the biomarker; and

3) (b) detecting the antibody biomarker antibody-NGAL complex; and

4) (c) evaluating the renal tubular cell injury status of the subject based on the level of NGAL present in the urine sample.

29. (canceled)

30. (new) A method for evaluating the renal tubular cell injury status of a mammalian subject, wherein the method comprises the steps of:

(a) detecting the presence of any neutrophil gelatinase-associated lipocalin (NGAL) in a urine sample obtained from a mammalian subject that is suspected of having or being prone to develop a renal tubular cell injury; and

(b) evaluating the renal tubular cell injury status of the subject based on the level of NGAL present in the urine sample.

31. (new) The method according to claim 30, wherein the detecting of NGAL is done by

(i) contacting the urine sample with an antibody for NGAL to allow formation of a complex of the antibody with any NGAL present in the urine sample; and

(ii) detecting the antibody-NGAL complex as a measure of the level of the NGAL.

32. (new) The method according to claim 30, wherein the renal tubular cell injury comprises an injury selected from the group consisting of an ischemic renal injury, a nephrotoxic injury, and another injury that affects the tubular cells of the kidney.

33. (new) The method according to claim 30, wherein the method is used to detect NGAL present in the first urine output of the subject immediately after the onset of renal tubular cell injury.

34. (new) The method according to claim 30, wherein the urine sample is obtained within 24 hours after an event that causes the mammalian subject to have, or to be prone to developing, the renal tubular cell injury.

35. (new) The method according to claim 30 wherein the urine sample is obtained within a period of time following the event selected from the group consisting of 6 hours, 4 hours, 2 hours, 1 hour, and 30 minutes.

36. (new) The method according to claim 35 wherein the event makes the mammalian subject develop or be prone to develop acute renal failure.

37. (new) The method according to claim 36 wherein the event is selected from the group consisting of: (a) a surgical procedure selected from the group consisting of cardiac surgery, coronary bypass surgery, cardiovascular surgery, and vascular surgery; (b) kidney transplantation; (c) administration of a nephrotoxic agent; and (d) the onset of a condition selected from the group consisting of stroke, trauma, sepsis, and dehydration.
38. (new) The method according to claim 36 wherein the event is one that causes the admission of the mammalian subject to an intensive care unit.
39. (new) The method according to claim 31 wherein the method is used to predict, diagnose, monitor or determine the likelihood of a renal tubular cell injury.
40. (new) The method according to claim 31 wherein the NGAL level is contrasted with a urinary NGAL value that distinguishes a mammalian subject that has a renal tubular cell injury from a mammalian subject that does not have a renal tubular cell injury.
41. (new) The method according to claim 31 wherein the step (c) of evaluating comprises contrasting the NGAL level with a urinary NGAL level that is predictive of the extent of the renal tubular cell injury.
42. (new) The method according to claim 41 wherein the NGAL level is contrasted with a urinary NGAL value that predicts subsequent development of acute renal failure, and wherein an NGAL level that is greater than the urinary NGAL value is indicative of a renal tubular cell injury that has or will subsequently develop to acute renal failure.
43. (new) The method according to claim 41 wherein the NGAL level is contrasted with a urinary NGAL value that predicts that the renal injury will not subsequently develop to acute renal failure, and wherein an NGAL level that is less than the urinary NGAL value is indicative of a renal tubular cell injury that has not and will not develop to acute renal failure.

44. (new) The method according to claim 31 wherein the urine sample is obtained after the mammalian subject has received a treatment for renal tubular cell injury, such that the NGAL level comprises a post-treatment NGAL assay result.

45. (new) The method according to claim 44, further comprising the step of determining from the post-treatment NGAL assay result if the treatment has been effective against the renal tubular cell injury.

46. (new) A method for the detection of a renal tubular cell injury in a mammal, including an ischemic renal injury and a nephrotoxic injury, comprising the steps of:

(a) contacting a urine sample from a mammalian subject that is suspected of having or being prone to develop a renal tubular cell injury with an antibody for neutrophil gelatinase-associated lipocalin (NGAL), to allow formation of a complex of the antibody and the NGAL; and

(b) detecting the antibody-NGAL complex.